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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,900	01/24/2006	Dominique P. Bridon	655772001000	6100
25226	7590	02/22/2011		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER BRADLEY, CHRISTINA	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 02/22/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/565,900	<b>Applicant(s)</b> BRIDON ET AL.	
	<b>Examiner</b> CHRISTINA BRADLEY	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73, 74, 76-86, 89, 90, 93, 116-124, and 131-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/01/2010, 05/24/2010, 02/04/2010, 09/04/2009</u>            | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 38,41-43,45,46,48-59,61,62,65,66,69-71,73,74,76-86,89,90,93,116-124 and 131-133.

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/2010 has been entered.
2. Claims 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73, 74, 76-86, 89, 90, 93, 116-124, and 131-133 are pending.

### **Claim Rejections - 35 USC § 102 - withdrawn**

3. The rejection of claims 38, 41, 48, 49, 65 and 116 under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Biochemistry, **1979**, 18, 690-7) is withdrawn in view of the amendment filed 02/04/2010. Liu et al. do not teach a purified insulin derivative comprising a single maleimido group at the  $\alpha$  amino group of the B1 residue.

### **Claim Rejections - 35 USC § 103 - withdrawn**

4. The rejection of claims 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73-86, 89, 90, 93, 116-124, 131 and 132 under 35 U.S.C. 103(a) as being unpatentable over Bridon et al. (WO 00/69900, foreign document citation No. 2 on the Information Disclosure Statement filed 01/21/2008) in view of Jones et al. (WO 95/05187, citation No. 6 on the Information Disclosure Statement filed 01/24/2006), Jonassen et al. (citation No. 9 on the Information Disclosure Statement filed 01/24/2006), Baudys et al. (citation No. 8 on the Information Disclosure

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Statement filed 01/24/2006), Bridon et al. (CA 2363712, citation No. 5 on the Information Disclosure Statement filed 01/24/2006) and Vajo et al. (Endocrine Rev., **2001**, 22, 706-717), and in further view of Uchio et al. ("Site-specific insulin conjugates with enhanced stability and extended action profile," Advanced Drug Delivery Reviews, **1999**, 35, 289-306) and Hinds et al. ("Synthesis and Characterization of Poly(ethylene glycol)-Insulin Conjugates," Bioconjugate Chem. **2000**, 11, 195-201) is withdrawn in view of the amendment, arguments and evidence of unexpected results filed 02/04/2010.

#### **Double Patenting - Withdrawn Rejections**

5. The provisional rejection of claims 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69, 71, 73-86, 89, 90, 93, 116, 117, 131 and 132 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-49 of copending application 11/982,033, in view of Bridon et al. (WO 00/69900, foreign document citation No. 2 on the Information Disclosure Statement filed 01/21/2008), Jones et al. (WO 95/05187, citation No. 6 on the Information Disclosure Statement filed 01/24/2006), Jonassen et al. (citation No. 9 on the Information Disclosure Statement filed 01/24/2006), Baudys et al. (citation No. 8 on the Information Disclosure Statement filed 01/24/2006), Bridon et al. (CA 2363712, citation No. 5 on the Information Disclosure Statement filed 01/24/2006) and Vajo et al. (Endocrine Rev., **2001**, 22, 706-717) is withdrawn in view of the amendment, arguments and evidence of unexpected results filed 02/04/2010.

6. The provisional rejection of claims 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73-86, 89, 90, 93, 116-124, 131 and 132 on the grounds of nonstatutory obviousness-type double

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patenting as being unpatentable over claims 1-58 of copending application 11/645,297, in view of Bridon et al. (WO 00/69900, foreign document citation No. 2 on the Information Disclosure Statement filed 01/21/2008), Jones et al. (WO 95/05187, citation No. 6 on the Information Disclosure Statement filed 01/24/2006), Jonassen et al. (citation No. 9 on the Information Disclosure Statement filed 01/24/2006), Baudys et al. (citation No. 8 on the Information Disclosure Statement filed 01/24/2006), Bridon et al. (CA 2363712, citation No. 5 on the Information Disclosure Statement filed 01/24/2006) and Vajo et al. (Endocrine Rev., **2001**, 22, 706-717) is withdrawn in view of the amendment, arguments and evidence of unexpected results filed 02/04/2010.

7. The provisional rejection of claims 38, 41-43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73, 74, 76-86, 89, 90, 93, 116-124, and 131-133 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 44 of copending application 11/981,474 is withdrawn because the '474 application was abandoned on 10/13/2010.

### **Double Patenting**

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 38, 41, 43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73, 74, 76-86, 89, 90, 93, 116-124, and 131-133 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 7,307,148. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 25 of U.S. Patent No. 7,307,148 recites insulin derivatives comprising an insulin molecule and a reactive maleimido-containing group for covalently bonding a blood protein, and conjugates of said insulin derivatives and the blood protein albumin. The species include: insulin B1-MPA, insulin B1-OA-MPA, and insulin B1-AEES2-MPA, wherein MPA is maleimidopropionic acid, OA is octanoic acid, AEES is amino ethoxy ethyl amino succinic acid and insulin is native human insulin identical to instantly claimed formula I. The albumin may be serum or recombinant (claim 6). The insulin derivatives and albumin-conjugates recited in claim 25 anticipate the instant claims.

10. In the response filed 02/04/2010, Applicant traversed the rejection on the grounds that the pending claims are not obvious in view of the claims of the '148 patent. This traversal has been fully considered but is not found persuasive because the rejection is based on anticipation not obviousness. MPEP § 804 states: "A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.,

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In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).”

In the instant case, the claims to a method of purifying insulin B1-MPA, insulin B1-OA-MPA, and insulin B1-AEES2-MPA in the ‘178 Patent anticipate the instant claims because these species meet all of the structural requirements of the claims. The fact that that patented claims are drawn to methods of purification does not negate the fact that the claims encompass insulin B1-MPA, insulin B1-OA-MPA, and insulin B1-AEES2-MPA.

11. Claim 42 is rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 7,307,148 (application No. 11/112,277 which issued as a patent since the mailing of the previous Office action) as applied to claims 38, 41, 43, 45, 46, 48-59, 61, 62, 65, 66, 69-71, 73, 74, 76-86, 89, 90, 93, 116-124, and 131-133 above, in further view of Vajo et al. (Endocrine Rev., **2001**, 22, 706-717). Vajo et al. teach native human insulin (formula I) and the analogs lispro, aspart, and glargine as examples of insulin for the treatment of diabetes (abstract). The teaching of Vajo et al. makes it clear that insulin analogs are obvious variants of insulin and could be substituted for the insulin in the conjugates recited in claim 25 of U.S. Patent No. 7,307,148. Applicant’s traversal filed 02/04/2010 does not specifically address why variants of insulin B1-MPA, insulin B1-OA-MPA, and insulin B1-AEES2-MPA wherein insulin is lispro, aspart or glargine are unobvious over insulin B1-MPA, insulin B1-OA-MPA, and insulin B1-AEES2-MPA.

### Conclusion



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12. No claims are allowed.

13. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRISTINA BRADLEY** whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/  
Primary Examiner, Art Unit 1654

cmb